UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,677	06/19/2008	Richard A. Bond	8077-003-US	1754

32301 7590 11/30/2011

CATALYST LAW GROUP, APC
5694 Mission Center Road
#519
SAN DIEGO, CA 92108

EXAMINER	
BORI, IBRAHIM D	
ART UNIT	PAPER NUMBER
1629	

MAIL DATE	DELIVERY MODE
11/30/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,677	BOND, RICHARD A.	
	Examiner	Art Unit	
	IBRAHIM D. BORI	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2011*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-8,16-21,25-27,40,41,49,57,65,73,84,92 and 99* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) _____ is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-8,16-21,25-27,40,41,49,57,65,73,84,92 and 99.

DETAILED ACTION

The restriction requirement of June 16, 2011 is herewith vacated on its entirety. The restriction mailed on June 16, 2011, was inadvertently made under 35 U.S.C. 121.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 1-8, 16-21, 25 and 26, drawn to a method for treatment of pulmonary airway disease in a subject suffering from pulmonary airway disease comprising administering a therapeutically effective amount of **a β-adrenergic inverse agonist** to the subject to treat the pulmonary airway disease.

- Group II, claims 40, 41, 49, 57, 65, 73, 84 and 92, drawn to a method for treatment of pulmonary airway disease in a subject suffering from pulmonary airway disease comprising administering to the subject:

  (1) a therapeutically effective amount of **a β-adrenergic inverse agonist** and

  (2) a therapeutically effective amount of **an additional agent selected** from the group consisting of: **a β_2-selective adrenergic agonist**; **a steroid**; **an anticholinergic drug; a xanthine compound**; **an anti-IgE antibody**; **a**

leukotriene modifier; and **a phosphodiesterase inhibitor** in order to treat the pulmonary airway disease.

- Group III, claim 27, drawn to a pharmaceutical composition comprising:

(a) nadolol in a quantity selected from the group consisting of 1 mg, 3 mg, 5, mg, 10 mg, 15 mg, 30 mg, 50 mg, and 70 mg; and

(b) a pharmaceutically acceptable carrier.

- Group IV, claim 99, drawn to a pharmaceutical composition comprising:

(a) a therapeutically effective amount of a **β-adrenergic inverse agonist**;

(b) a therapeutically effective amount of **a second therapeutic agent** effective to treat a pulmonary airway disease, the second therapeutic agent being selected from the group consisting of: **a β_2-selective adrenergic agonist**, **a steroid**, **an anticholinergic drug**, **a xanthine compound**, **an anti-IgE antibody**, **a leukotriene modifier**, and **a phosphodiesterase IV inhibitor**; and

(c) a pharmaceutically acceptable carrier.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the claimed invention is the use of β-adrenergic inverse agonist in a method to treat pulmonary airway disease. This special technical feature does not define a contribution over prior art as evidenced by

WO0224198 to Bond. Bond teaches use of β-adrenergic inverse agonist in a method to treat allergic or inflammatory disorders exemplified by chronic obstructive pulmonary disorder (a pulmonary airway disease). There is lack of unity *a posteriori.* Therefore, the claims lack novel technical feature and are not so linked as to form an invention.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. *Specific β-adrenergic inverse agonist.* Applicant must elect a single β adrenergic inverse agonist. For example, β-adrenergic inverse agonist listed on claim 2.

B. *Specific β-adrenergic inverse agonist subtype*. Applicant must elect a single β-adrenergic inverse agonist subtype. For example, β-adrenergic inverse agonist subtype listed on claims 4-8 and 41.

C. *Specific pulmonary airway disease.* Applicant must elect a single pulmonary airway disease. For example, pulmonary airway disease listed on claim 18.

D. *Specific administration route*. Applicant must elect a single administration route. For example, administration route listed on claim 16.

E. *Specific additional agent*. Applicant must elect a single additional agent. For example, additional agent listed on claim 40.

F. *Specific additional agent subtype*. Applicant must elect a single additional agent subtype. For example, additional agent subtype listed on claims 41, 49, 57, 65, 73, 84, and 92.

Applicant is required to elect a single β-adrenergic inverse agonist or a single β-adrenergic inverse agonist subtype, or a single pulmonary airway disease, or a single administration route, or a single additional agent and a single additional agent subtype **commensurate** with the elected invention. For example, claim 2 indicates that the β-adrenergic inverse agonist is selected from a group consisting of the list disclosed therein and claim 4 indicates that β-adrenergic inverse agonist subtype is selected from a group consisting of the list disclosed therein. Should Applicant elect Group I, Applicant should then identify the one a single β-adrenergic inverse agonist, a single β-adrenergic inverse agonist subtype, a single pulmonary airway disease, and a single administration route by their proper chemical name and by their proper chemical structure and any other identifiers, and indicate which claims encompass the elected species.

Applicant is required, in reply to this action, to **elect a single species** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species listed above are not regarded as being of similar nature because each β-adrenergic inverse agonist subtype has distinct chemical structures, chemical properties, modes of action and reactivity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Time for Reply

Applicant is reminded that 1-month (not less than 30 days) shortened statutory period will be set for reply when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program. MPEP § 809.02(a).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IBRAHIM D. BORI whose telephone number is (571)270-7020. The examiner can normally be reached on Monday through Friday 8:00AM-5:00PM(EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY S. LUNDGREN can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/IBRAHIM D BORI/
Examiner, Art Unit 1629

/Jeffrey S. Lundgren/
Supervisory Patent Examiner, Art Unit 1629